

E C A M A

Mr Arthur Neal, Director, Program Administration
National Organic Program
USDA—AMS—TMP—NOP
1400 Independence Ave., SW., Room 4008
So. Ag Stop 0268
Washington, DC 20250

Via E-mail: National.List@usda.gov

16 August 2005

Dear Mr Neal,

**RE: USDA, Agricultural Marketing Service Docket Number TM-04-07
concerning 7 CFR Part 205, National Organic Program Sunset Review process.**

ECAMA is the European Citric Acid Manufacturers Association, a sector group of CEFIC. We would like to take the opportunity to make the following comments on the Sunset Review of the 2002 National List.

ECAMA would like to ask for continuance of citric acid, and its salts, sodium citrate, potassium citrate, and calcium citrate as these are listed on the National List. For many years, we have provided citric acid and its salts to our customers for their organic product formulations and would like to provide support for these materials:

§ 205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as “organic” or “made with organic (specified ingredients or food groups(s))”

(a) Nonsynthetics allowed:

Acids (Alginic; Citric - produced by microbial fermentation of carbohydrate substances; and Lactic).

(b) Synthetics allowed.

Calcium citrate.

Potassium citrate.

Sodium citrate

Citric acid has been described as 'nature's acidulant', occurring in a wide variety of fruits and playing a central role in human and animal metabolism. Citric acid is produced by fermentation processes using natural, renewable raw materials such as molasses and other carbohydrates.

Since citric acid is a natural product manufactured by fermentation, and since its salts are manufactured by neutralising the acid with a mineral salt sources of sodium, calcium, or potassium it should even be considered to reclassify Calcium citrate, Potassium citrate, Sodium citrate to the non-synthetics as per § 205.606.

ECAMA recommends that Citric acid, Calcium citrate, Potassium citrate, and Sodium citrate remain on the list as per the original evaluation by the NOSB, that citric acid and its salts are:

- (1) Not harmful to human health or the environment
- (2) Necessary because of the unavailability of alternatives
- (3) Consistent and compatible with organic practices

Substantial safety and toxicology data exists with JECFA and US FDA that citric acid and its salts are not harmful to human health or the environment.

Citric acid and its salts are used as acidifiers, pH regulators and stabilisers by formulators of various organic products.

Evaluation criteria according to Federal Register / Vol. 70, No. 116 / Friday, June 17, 2005 / Proposed Rules 35181 (Appendix):

CATEGORY 1 - No adverse impacts on humans or the environment

1. Citric acid and its salts do not contribute any adverse impact to the environment or humans either during production or end-use. During the manufacturing processes, any waste will be discharged to the municipal sewage treatment plant and will be present in only trace amounts.
2. There is no significant impact on the environment from Citric acid and its sodium, potassium and calcium salts. Citric acid and citrates are easily degraded by micro organisms found in the water and soil since Citric acid and its sodium, potassium and calcium salts are natural components of plants and animals. Citric acid plays an important role as an intermediate metabolite of the Krebs cycle in virtually all organisms. Therefore, they do not persist in the environment. Minerals will naturally degrade. Any waste materials (e.g., finished products such as food or beverages) will be composted, sent to land fills or treated in wastewater treatment plants. These actions will not result in an adverse effect on the environment.
3. Citric acid and its sodium, potassium and calcium salts are not on the list, nor do they contain, inerts from list 1, 2 or 3.
4. There is no potential for detrimental chemical interaction with other materials used.
5. There are no adverse biological and chemical interactions in agro-eco-systems.
6. There are no detrimental physiological effects on soil organisms, crops, or livestock.
7. There is no toxic or other adverse action of the material or and there are no breakdown products.
8. There is no undesirable persistence or concentration of the material or breakdown products in the environment.
9. There are no harmful effects on human health.

Citric acid (E330), sodium citrate (E331), calcium citrate (E333) and potassium citrate (E332) are permitted EU Food Additives and may be used quantum satis. According to the JECFA (Joint Expert Committee on Food Additives of the WHO/ FAO), these products may be used without limitation, according to Good Manufacturing Practice. The US Food and Drug Administration classifies citric acid, sodium citrates, calcium citrates and potassium citrates as GRAS (Generally Recognized as Safe) food ingredients.

Please find attached material safety data sheet for citric acid.

CATEGORY 2 - Substances are essential for organic production.

Citric acid and its sodium, potassium and calcium salts are produced by a fungal fermentation using natural constituents like glucose syrups, sugar or molasses. Citric acid and its sodium, potassium and calcium salts contribute a unique attribute to

foods and beverages, thus allowing many more organic products to be formulated and marketed to the consumer. Citric acid can be regarded as an indispensable acidifying agent that hardly could be substituted.

Besides the main use of citric acid in the manufacture of soft drinks, citric acid and its salts are also used extensively in the processing of a wide variety of foods, in pharmaceutical preparations and for a range of technical and industrial applications.

Examples for food and organic food applications are:

Soft Drinks, Wine, Candies, Canned Fruits and Vegetables, Jams and Jellies, Fruit Preparations, Gelatin Desserts, Processed Cheese, Sea Food, etc

The main functions of citric acid and the citrates in (organic) foods and beverages can be summarised as follows:

- as a flavour adjunct, to improve taste
- as a pH control agent for example for gelation control, buffering and preservative enhancement
- and as a chelating agent where it improves the action of antioxidants and prevents spoilage of foods such as seafood.

CATEGORY 3 - Substances are compatible with organic production practices

Citric acid, Calcium citrate, Potassium citrate, Sodium citrate are listed at § 205.605

Citric acid, Calcium citrate, Potassium citrate, Sodium citrate do not contain the synthetic ingredients in the following categories:

- a. copper and sulfur compounds
- b. toxins derived from bacteria
- c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals*
- d. livestock parasiticides and medicines
- e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners

*exemption: the sodium, potassium and calcium salts of citric acid are salts of the minerals sodium, potassium and calcium as such.

Yours sincerely,
Michael O'Donovan, Barbara Katzbauer / ECAMA Applications Technology Group

<http://www.ecama.org>